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European Federation of Pharmaceutical Industries and Associations

Position on shortcomings of the Summary of Product Characteristics and the Package Leaflet and proposals to resolve them

EFPIA fully supports providing comprehensive, accurate and up-to-date information on medicinal products both for health care professionals and patients. Such information must be easily accessible. It needs to be adjustable to the need of the individual patient to provide the necessary level of detail for the most effective and safe use of the medicine.

To fully realise this and at the same time taking advantage of the current technological advances alternative mechanisms for dissemination such as internet or mobile devices or other methods like e.g. direct print-outs at dispensing level should be explored. This will facilitate significantly faster updates of information for health care professionals and patients in all EU languages.

EFPIA sees the necessity to start the process of introducing new methodologies for procuring product information in more user-friendly structures and styles. People look for information on the internet. Not only younger people but an increasing number of all age groups takes benefit of the steadily growing number of electronic health information and applications. Yet, the quality of these sources of information greatly varies. A single trusted source of authorised product information could support the empowerment of patients by providing the best available knowledge about a medicine. Containing only health authority approved information it could serve as a baseline with reliable facts. This approach fits also into the European Commission's Digital Agenda (i.e. eHealth and Ageing).

Electronically available systems could also better meet the need of disabled people (e.g. audio versions) or of people with specific requirements of information representation (e.g. video, charts).

Background

Patient organisations have been highlighting the shortcomings of Package Leaflets (PLs) for a long time. As required by Directive 2010/84/EC the European Commission shall produce by 1 January 2013 an assessment report on current shortcomings in the Summaries of Product Characteristics (SmPCs) and the PLs and their value to health care professionals (HCPs) and patients. Furthermore the Commission shall, if appropriate, make proposals to improve the readability, layout and content of the SmPC and the PL "*…to better meet the needs of patients and HCPs*."

Product information (information on the immediate or outer packaging, including PL) is regulated in detail by EU Directive 2001/83/EC and its amendments and various guidelines (i.e. Readability- and SmPC-guidelines and QRD template). Therefore further improvements to information for HCPs and patients on medicinal products will require changes of the legislation and the guidelines.

In the following EFPIA will:

I. Analyse the SmPC and the PL
II. Make proposals how shortcomings could be overcome by amending the readability, layout and content
III. Explore alternative methods of dissemination of SmPC and PL

I. Analysis of SmPC and PL

The SmPC has to serve various purposes:

- Core dossier document for Marketing Authorisation Holder
- Main official information source for HCPs
- Basis for PL
- Legal document together with the PL regarding liability of the company

These multiple purposes do not allow a targeted approach and result in lengthy documents. On one hand Marketing Authorisation Holders find it difficult to address e.g. risks from clinical trials and post-authorisation spontaneous reporting satisfyingly. On the other hand HCPs do not find the essential prescribing information easily and miss information like recommendations for communication during the patient's visit.

Several publications describe the shortcomings of SmPC and PL:

- Too rigid legislation, guidelines and templates for industry to adapt to the needs of HCPs and patients
- The provision of SmPCs and PLs in paper format, combined with the current structure and length of these documents does not help users to find information quickly
- The language of the documents often does not reflect the literacy levels or language skills of the readers
- Multi-language package leaflets are even more complex and technically challenging
- Patients and HCPs recommended that benefits and risks must always be communicated together, clearly explaining the benefits on one hand and the risks on the other. Where possible, there should also be a clear description of the factors that could have an impact on the benefits or the risks for individual patients

Based on the shortcomings of the current SmPC and PL, improvements in the following areas would be necessary:

- Language that reflects the readers' literacy level
- Structure and layout (e.g. including drawings) that help the reader to navigate and find the information necessary
- Accessibility that ensures fast and easy access to reliable and up-to-date information (single access point)
- QRD templates for all EU procedures to be less rigid, taking more patient needs into account (EMA and national regulators flexible alignment) and reflecting final PL including punctuation.

These proposed improvements will be detailed in the following sections.

II. Proposals to amend the readability layout and content of the product information

Since the SmPC and the PL are the first and often only official information sources about a drug, they play a critical role, be it for HCPs or for patients. The PL for instance is the only information patients take home after dispensing of a prescription or of an over-the-counter medicine at a pharmacy. Therefore, as a main principle, any PL should support patient's adherence to treatment and focus on improving health outcomes.

- EFPIA proposes the following subheadings for this information (deviations from QRD-template are printed in **bold**)
    - Product details
    - Therapeutic indications and Benefits
        - Therapeutic indications
        - Benefits
    - **Dosage and safe use of the medicinal product**
    - Risks
    - **General information (storage, …)**
    - **Special Populations (paediatric, geriatric, patients with impaired liver function, patients with impaired kidney function…)**

- In the benefit section information on the benefit of the medicinal product should be described in a non-promotional language. Graphical presentation of the data, such as Forrest-plots, might be used to illustrate the benefit in the HCP-information.
- Risks need to be set in relation to the potential benefit so that HCPs and patients are able to weigh both for the individual case and make an informed decision.
- Instructions for the patients should be as concrete as possible (e. g. a glass of water instead of sufficient water).
- Placement of illustrations with drawings where useful and not strictly to be placed at the end

Any solution should be elaborated in cooperation with representatives of patient organizations as well as HCPs and other stakeholders – ideally coming from countries with different health care systems.

III. Proposal for future methods of dissemination of the product information

Eventually, printed PL can get lost or become outdated. Otherwise, technological advances such as internet or mobile devices provide opportunities to make this information available anywhere and updated at any time.
Although there is already much information on medicinal products available on the internet, in most countries a single source of information that is reliable and accepted as *the* official source by HCPs and patients is still missing.

EFPIA proposes to explore the possibility of addressing both patients and HCPs via one tool. The main rationale would be that patients should not per se be excluded from information addressed to the prescriber. To facilitate this, the information for HCPs and patients on all authorised products could be made available electronically by a single trustful source in a way that allows getting speedily to the preferred level of information (e.g. words marked with hyperlinks leading to an underlying dictionary). Electronic dissemination is key to update this information speedily and to present the information tailored to the specific needs of HCPs and patients. A patient friendly option would be that this system would be able to highlight any critical changes (e.g. new warnings) to the product information.

Proposed structure of a revised structure for product information:

- At first level a list of the brand names of all products could be given. Each product should get a "homepage" with basic administrative information where the user will find two options for further search:
  - Information for HCPs (it might be explored how this could be displayed in the software of prescribers for direct access)
  - Information for patients that reflects the HCP-information in an easily understandable language. The structure remains the same but some chapters might have some different information under the same headings because patients search in another way than HCPs. In addition, it should be ensured that the patient information remains brief and concise.

Many European initiatives and legislative stimulate the use of electronic systems in health systems:
The High Level Pharmaceutical Forum recommended accelerating the information to citizens in effective communication formats, by both electronic and non-electronic means.
EFPIA's proposed solutions would also facilitate the European Commission's obligation under the Cross-Border Healthcare Directive (Directive 2011/24/EU, Art. 11 (d), to adopt "measures to facilitate the comprehensibility of the information to patients concerning ... the instructions included on the use of the product, including an indication of active substances and dosage").

The Green Paper on mobile Health ("mHealth") released in June 2014 also suggests that mHealth „ could contribute to a more efficient way of delivering care through better planning, reducing unnecessary consultations and better prepared professionals receiving guidance on treatment and medication."Pharmaceutical companies and some regulatory medicines agencies have already started to disseminate isolated electronically available information platforms.

The European Medicines Agency (EMA) has stated that applicants can make requests to include **quick response (QR) codes** as part of the initial marketing authorisation application or after the medicine is authorised and the Coordination group of national medicinal agencies (CMDh) has issued a position paper on the use of QR codes to provide information about the medicinal product in April 2014.

The position paper also contains a survey what kind of information linked with such a code (e.g. product information, additional risk minimization material, videos) is allowed in the various member states. However, QR codes should not be applied to the outer package because they may interfere with the verification of the safety features (2D Matrix Codes).

Initiatives around the globe:

Other regions have already implemented electronic information: The Australian TGA explains Consumer Medicines Information (CMI) as following (http://www.tga.gov.au/consumers/information-medicines-cmi.htm): “TGA regulations require that the CMI be made available to consumers either in the pack or in another manner that will enable the information to be given to the person to whom the medicines are administered or otherwise dispensed.” Also the FDA (Docket No. FDA–2011–N–0849) is exploring rapid access to safety updates via electronic media: “In an effort to make revised safety labeling available as soon as possible after the changes required under FDAAA are approved, FDA has recommended that application holders post the revised labeling on their Web sites within 10 days of approval.”

EFPIA finds that in this context new technological platforms for providing product information should be explored in the European Union, while keeping in mind that access to information must also be ensured for patients who do not (yet) have access to electronic media.

<u>Options to explore include</u>:

- Using an electronic medium will facilitate the presentation of information that is specific to the needs of HCPs and patients in a very efficient and quick way.
- Links in the table of content can make information easily accessible.
- It allows meeting the needs of people with disabilities and special requirements for information representation (audio versions, font size flexibility, videos, charts etc.).
- An electronic medium makes information available anywhere and at any time. In addition, it ensures quicker information updates, if needed and tailor-made information by search functions.
- A transfer from paper to electronic product information will also have a positive effect on the environment, considering all the paper that is used for the frequent updates of paper package leaflets.
- As a mid-term task a web-based information system should be designed and installed that is easily accessible also from mobile devices. As pointed out already this should be complementary to many other health applications available on the internet. Instead of “package leaflets” in the individual packages. There should be the possibility for the patient to get the correspondent “product information” printed in the pharmacy and in the HCP’s office or via other technologies.

The electronic-only product information should be introduced in a stepwise approach (over several years):

- e-version and identical paper leaflet in parallel in the beginning to test the functionalities and acceptance
- At a later point in time when the legislation has been changed so that paper leaflets are not obligatory any more: phase-out of paper and e-version alone.

Consideration should be given to changing the legislation to require patient information to be provided but allow Member States to determine the appropriate method of dissemination. This flexibility would allow Member States to be more prepared to implement electronic dissemination (only, or e.g. in combination with pharmacy print out) sooner and as appropriate to the state of electronic media in their respective country. In some countries where there are already well established electronic databases, it may be possible to use these systems in advance of a European level system.

References:

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As of 15 October 2014